

ABSTRACT OF THE DISCLOSURE

The present invention relates generally to the production of recombinant human uteroglobin (rhUG) for use as a therapeutic in the treatment of inflammation and fibrotic diseases. More particularly, the invention provides processes, including broadly the steps of bacterial expression and protein purification, for the scaled-up production of rhUG according to current Good Manufacturing Practices (cGMP). The invention further provides analytical assays for evaluating the relative strength of in vivo biological activity of rhUG produced via the scaled-up cGMP processes.